510(K) Summary

K100434

JUL 28 2010

ICU MEDICAL INC.
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Tracy S. Best, Sr. Regulatory Affairs Specialist
Preparation Date: 06/23/2010

Summary of Safety and Effectiveness for the:

Trade Name:	CLAVE® Neutron™
Common Name:	Needleless Connector, Closed Access
Classification Name:	21 CFR 880.5440, Class II Device, 80FPA & 80LHI, Accessory

Legally Marketed Predicate Devices for Substantial Equivalence:

*K970855 – CLAVE® Connector – ICU Medical Inc.
*K021692 – CLC2000® Catheter Patency Device – ICU Medical, Inc.
*K083723 – A6 Luer Access Device – B. Braun Medical, Inc.

Rationale for Substantial Equivalence:

The CLAVE Neutron is substantially equivalent to all three predicates by providing a normally closed, needleless connection and a route to deliver blood and fluids to a patient through a vascular access device. All three predicate devices and the proposed device are free of steel needle components and designed such that the use of a needle in the device would render them inoperable. This design feature passively aids in the prevention needlestick injury as needles cannot be introduced into the system during use.

The anti-displacement feature of the CLAVE Neutron is substantially equivalent to both the CLC2000 and the A6 in that it prevents negative displacement.

The power injectable feature is substantially equivalent as the A6 Luer Access Device which allows the infusion of contrast media at 10mL per second at a maximum pressure of 300psi. The CLAVE Neutron allows infusion of contrast media of 10mL per second with a maximum pressure of 350psi.

Components of the CLAVE Neutron are made from materials that are substantially equivalent to the predicate devices. Comprehensive biocompatibility testing for the CLAVE Neutron is included in this Submission.

The CLAVE Neutron was subjected to a variety of functional tests including microbial ingress and performance criteria which prove it to be substantially equivalent to the predicate devices. Results of the testing demonstrate that there are no new issues of Safety and Efficacy that are raised with the introduction of the CLAVE Neutron.

Description of Submitted Device:

The CLAVE Neutron is a normally closed, bidirectional connector that incorporates a unique silicone valve within the fluid path. The unique valve prevents fluid displacement, both positive and negative at all times, including when the device is accessed. There are four known causes of displacement associated with needleless connectors. They are:

1. **Connection or Disconnection of an Adaptable Luer Device.** Fluid displacement occurs when a luer is inserted, or removed, from a connector by *displacing* a specific volume. This is also commonly known as positive or negative pressure when describing connectors.
2. **Syringe Plunger Rebound.** This occurs when a flush has been done using a standard syringe. Once the syringe is emptied, the clinician has the ability to *compress* the syringe plunger in an effort to infuse all available solutions which, once released by the clinician's hand, will rebound and cause negative fluid displacement.
3. **Patient Vascular Pressure Changes.** Routine events such as coughing, sneezing, crying and bearing down can cause a temporary increase in a patient's vascular pressure. This pressure can cause negative fluid displacement back through a standard needleless connector.

4. **IV Bag Run Dry.** When an IV solution bag is allowed to empty, the normal gravity infusion pressure which is caused by the weight of the fluid hung at 36" head height diminishes to little or zero positive pressure. Normal patient vascular pressure may then overcome the fluid head height pressure and cause negative fluid displacement back through a standard needleless connector.

Intended Uses of the CLAVE® Neutron™:

CLAVE Neutron is a normally closed, bidirectional connector intended for use as an accessory to an intravascular catheter placed in the vein or artery. The device may be used for the administration of blood and fluids to patients, including pediatrics and immunocompromised patients. The device may also be used with power injector procedures up to 10mL per second of contrast media and a maximum pressure of 350psi. The device incorporates a technology that will prevent fluid displacement resulting from the following: Connection or disconnection of a luer; syringe plunger compression; patient vascular pressure changes, such as coughing or sneezing; and IV solution container run-dry. The CLAVE Neutron incorporates a pre-slit septum that does not require the use of needles and will therefore passively aid in the reduction of needlestick injuries.

Safety and Performance:

The CLAVE Neutron is intended for use on a patient's vascular access device including pediatrics and immunocompromised patients. As discussed in the Executive Summary, the CLAVE Neutron incorporates proprietary design features from the CLAVE Needleless Connector. Specifically the pre-slit septum and the internal cannula of the predicate CLAVE which are used to transfer fluid to the patient's catheter, are identical in design. These two components are the functional components which prohibit bacterial transfer. *Microbial Ingress* testing as provided in this submission demonstrates that the CLAVE Neutron in comparison to the CLAVE was equivalent in its ability to prevent bacterial ingress. Said testing shows that the device will prevent bacterial ingress completely if used in accordance with the directions for use. The prevention of bacterial ingress is specifically important for pediatrics and immunocompromised patients that would otherwise be at risk of infection.

In Bouza[1] (2003), the CLAVE was found in a randomized clinical trial to independently reduce catheter hub and tip bacterial colonization. The patient population for the study was immunocompromised, intensive care patients at the Department of Cardiovascular Surgery, Hospital General Universitario, University of Madrid, Madrid, Spain. The identical CLAVE pre-slit septum component used in the study, is still used in the CLAVE today and also in the proposed CLAVE Neutron. This study demonstrates that the specific CLAVE split-septum design may safely be used in immunocompromised patient populations.

In Maragakis[2] (2006), the CLAVE was clinically studied in pediatric and immunocompromised patient populations. In this study, pediatric ICU and pediatric oncology service patients at the John's Hopkins Hospital in Baltimore Maryland were observed for Catheter Related Bloodstream Infection Rates. The identical CLAVE pre-slit septum component used in this study, is still used in the CLAVE today and also in the proposed CLAVE Neutron. This study demonstrates that the specific CLAVE split-septum design may safely be used in pediatric and immunocompromised patient populations.

The CLAVE Neutron has been tested in accordance with its product specifications which accommodate known functional requirements for Critical Care, Neonatal Care and Pediatrics.

The CLAVE Neutron is individually packaged and pre-sterilized in a peel type pouch. The device can be included as part of a kit or set – as the physician may prescribe. ICU Medical performs analysis and design verification testing based on predetermined criteria, which is documented in the Performance Specification contained in this submission. All testing meets these performance criteria as defined for the device, including power infusion up to 10mL per second of contrast media. The design of the device allows it to accept a male luer as defined by ISO 594-1 and ISO 594-2 which is considered to be an industry standard.

ICU Medical has also performed testing that is recommended by the guidance document "*Intravascular Administration Sets Premarket Notification Submissions [510(k)]*" and we have included that successful testing as part of this submission.

Technological Characteristics and Substantial Equivalence Table:

Specification:	CLAVE®	CLC2000®	Braun A6	CLAVE® Neutron™
510(k) Approval	K970855	K021692	K083723	This submission
Functional use	Needleless connector	Needleless Connector with anti-reflux	Needleless connector with anti-fluid displacement and power injectable	Needleless connector with anti-fluid displacement and power injectable
Patient Populations[1]	Adults, Pediatrics and Immunocompromised patients	Adults	Adults	Adults, Pediatrics and Immunocompromised patients
Residual Volume	0.06mL	0.07mL	0.30mL	0.14mL
Gravity Fluid Flow	100mL/min	200mL/min	Unavailable for test	100mL/minute
Syringe Disconnect: Fluid Displacement	Negative Displacement	Positive Displacement	Positive Displacement	Integral valve prevents displacement, both positive and negative*
Syringe Plunger Compression: Fluid Displacement	N/A	N/A	N/A	Integral valve prevents displacement, both positive and negative
Patient Pressure: Fluid Displacement	N/A	N/A	N/A	Integral valve prevents displacement, both positive and negative
Bag Run-Dry: Fluid Displacement	N/A	N/A	N/A	Integral valve prevents displacement, both positive and negative
Multiple Activations	96 intermittent 3 extended time	96 intermittent 3 extended time	Unavailable for test	96 intermittent 3 extended time
Positive Leak Pressure	60psig	60psig	Unavailable for test	45psig**
Negative Leak Pressure	-8.5psig	-8.5psig	Unavailable for test	-8.5psig
Luer Retention	ISO 594-1 (5.4)	ISO 594-1 (5.4)	Unavailable for test	ISO 594-1 (5.4)
Component Assembly	>5lbf-in	>15lbf-in	Unavailable for test	>20lbf-in
Chemical Compatibility	Lipids, Alcohol	Lipids, Alcohol	Unavailable for test	Lipids, Alcohol
Power Injectable	N/A	N/A	10mL/sec of contrast media and < 300psi.	10mL/sec of contrast media and < 350psi.
Sterilization Method	Gamma or E-beam	Gamma or E-beam	Gamma or E-beam	Gamma or E-beam
Packaging	Peel pouch	Peel pouch	Peel pouch	Peel pouch
Materials	Polyester; Silicone; and ABS or Polycarbonate	Polyester; Silicone; Stainless Steel; Polypropylene; and Polycarbonate	Polycarbonate; rubber; silicone	Polyester; Silicone; ABS or Polycarbonate; and Nylon

*A single, integral valve in the CLAVE Neutron is used to prevent the four forms of fluid displacement. This fluid displacement feature is substantially equivalent to the fluid displacement feature of all three predicate devices during the disconnection of a luer. For the additional three fluid displacement features (Syringe Plunger Compression, Patient Pressure and Bag-Run Dry), the valve operates in the identical manner which renders these new features not significantly different from the predicate devices.

**45 psig is adequate to prevent positive pressure leakage from a patient's line and is therefore not significantly different from the predicate devices.

Conclusion:

As demonstrated by the table above, there are equivalent features and functional uses between devices. Differences are in materials; maximum pressure; residual volume; and additional types of displacement that the CLAVE Neutron is able to accommodate. Materials are tested to the latest ISO 10993 standards; the unique design allows the additional pressure up to 350psi; residual volume is less than half of the A6 predicate due to an internal fluid path versus an external fluid path; and additional displacement types are due to the manner in which the valve operates on the CLAVE Neutron. These differences do not introduce any new safety or efficacy risks to the patient.

The operational characteristics are equivalent to luer needleless connection technology and intended use when compared to the three predicate devices. The proprietary technology in the CLAVE Neutron is unique to this type of product and is confidentially discussed further in this submission.

Materials, performance, operational features, environment of use, and connection methodology of the submitted device compared to the predicate devices show that they are substantially equivalent

and that they are safe and effective for their intended use as demonstrated and supported in the performance testing according to the product specification, included in this submission.

Clinical and Non-Clinical Data:

There is no clinical data included in this submission.
Non-Clinical data is included in the *CLAVE Neutron Design Verification Report* in the submission as simulated use environment testing. The testing subjected the CLAVE Neutron to a series of performance testing, biocompatibility, and microbial ingress challenges to verify the safe and effective use of the device. This testing demonstrates that there are no differences between the predicate and proposed device that raise any new issues of safety or effectiveness. This proprietary data is included in this submission.

[1] Bouza, E, Munoz, P, Lopez-Rodriguez, J, Jesus Perez, M, & Rincon, C, et. al, (2003). A Needleless closed system device (clave) protects from intravascular catheter tip and hub colonization: a prospective randomized study. *Journal of Hospital Infection, 54*, 279-287.

[2] Maragakis, L, Bradley, K, Song, X, Beers, C, & Miller, M, et. al, (2006). Increased catheter-related bloodstream infection rates after the introduction of a new mechanical valve intravenous access port. *Infection Control and Hospital Epidemiology, 27*, 67-70.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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AUG 9 - 2010

Mr. Tracy Best
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Re: K100434
Trade/Device Name: Clave® Neutron™
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long Term Intravascular Catheter
Regulatory Class: II
Product Code: FPA
Dated: June 24, 2010
Received: June 25, 201

Dear Mr. Best:

This letter corrects our substantially equivalent letter of July 7, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100434

Device Name: Clave® Neutron™

Indications for Use:

CLAVE Neutron is a normally closed, bidirectional connector intended for use as an accessory to an intravascular catheter placed in the vein or artery. The device may be used for the administration of blood and fluids to patients, including pediatrics and immunocompromised patients. The device may also be used with power injector procedures up to 10mL per second of contrast media and a maximum pressure of 350psi. The device incorporates a technology that will prevent fluid displacement resulting from the following: Connection or disconnection of a luer; syringe plunger compression; patient vascular pressure changes, such as coughing or sneezing; and IV solution container run-dry. The CLAVE Neutron incorporates a pre-slit septum that does not require the use of needles and will therefore passively aid in the reduction of needlestick injuries.

Prescription Use __XX__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman 8/5/10

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100434